 K031391

JUN 2 0 2003

Ophthalmic Technologies Inc.
Special 510(k) Submission
OTI-Scan HF Module
April 24, 2003
510(k) Summary

(1) Submitter Information

Name: Ophthalmic Technologies Inc.

Address:

Ophthalmic Technologies Inc.
37 Kodiak Crescent, Unit 16
Downsview, Ontario, Canada M3J 3E5

Telephone number:

416-631-9123 • 1-800-517-4444

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: April 24, 2003

(2) Name of Device

Trade Name: OTI-scan HF Module
Common Name: Ophthalmic B-scan system
Classification name: System, Imaging, Ultrasonic, Ophthalmic, 980IYO

(3) Equivalent legally-marketed devices.

OTI-scan K030770

(4) Description

The OTI-scan HF module is an ultrasonic ophthalmic B-scan system that uses the principles of sonar (pulsed ultrasound) to visualize and measure the interior of the eye with high-frequency transducers to obtain better accuracy.

(5) Intended Use

The *OTI-scan* HF module is an option for the OTI-scan (K030770), a multi-purpose personal-computer-based ultrasonic B-scan diagnostic system for ophthalmic applications.

(6) Performance Data

(a) Non-clinical tests

The HF Module has had accuracy tests, ultrasonic emissions tests, electrical safety tests, and software validation tests.

(b) Clinical tests

Not required.

(c) Conclusions

The HF Module is equivalent in safety and efficacy to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2003

Ophthalmic Technologies, Inc.
% George H. Myers, Sc.D.
Official Correspondent
Medsys, Inc.
377 Route 17 South
HASBROUCK HEIGHTS NJ 07604

Re: K031391
Trade Name: OTI-scan HF-Module System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: April 29, 2003
Received: June 3, 2003

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the OTI-scan HF-Module System, as described in your premarket notification:

Transducer Model Number

35 MHz B-Scan
50 MHz B-Scan

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA

may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use Form

Page 1 of 1

510(k) Number (if known): K03891

Device Name: OTI-scan 35 mHz B-scan transducer

Intended Use: Transducer for B-scans with OTI-Scan HF Module

Mode of Operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	COLOR DOPPLER	POWER (AMPLITUDE) DOPPLER	COLOR VELOCITY IMAGING	COMBINED (SPECIFY)	OTHER (SPECIFY)
Ophthalmic		x								
Fetal										
Abdominal										
Intra-operative (specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Intra-luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____

(Per 21 CFR 810.109)

(Optional Format 1-2-96)

David A. Lehmann

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

K021291

Diagnostic Ultrasound Indications for Use Form

Page 1 of 2

510(k) Number (if known): K031391

Device Name: OTI-Scan 50 Mhz B-scan transducer

Intended Use: Transducer for B-scans with OTI-Scan HF Module ophthalmic system

Mode of Operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	COLOR DOPPLER	POWER (AMPLITUDE) DOPPLER	COLOR VELOCITY IMAGING	COMBINED (SPECIFY)	OTHER (SPECIFY)
Ophthalmic		x								
Fetal										
Abdominal										
Intra-operative (specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Intra-luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 810.109)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

K031391